10/528,612 06/25/2007 02/26/2007

### Remarks/Arguments:

## I. ACTION SUMMARY

Claims 1-3, and 12 were pending. Claims 4-11 and 13-15 were canceled.

In response to the official action, Claim 1 has been amended and Claim 3 has been cancelled.

### II. PRIORITY

This application is a 371 of PCT/GB03/04211 filed September 29, 2003 which claims benefit under 35 U.S.C. §119 (a-d) to United Kingdom 0222909.4, filed October 3, 2002.

Applicants acknowledge the claim to priority.

#### III. INFORMATION DISCLOSURE STATEMENT

The Examiner states that the information disclosure statements (IDS) submitted on April 17, 2006, August 22, 2005, and March 21, 2005 are in compliance with the provisions of 37 CFR 1.97 and accordingly, the information disclosure statements have been considered by the examiner.

Applicants note the Examiner has considered the IDS's.

### IV. RESTRICTION/ELECTION

# A. Election: Applicant's Response

Applicant's election of Group I, claims 1-3, and 12 without traverse in the response filed on January 12, 2007 is acknowledged by the Examiner, the requirement is made FINAL.

Applicants acknowledge this.

### V. REJECTION(S)

# Claim Rejections - 35 USC § 112

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements, see MPEP § 2172.01. The Examiner states that the invention is drawn to "an improved process" for the production of the compound of Formula (I), see, specification, p. 2, lines 4-5 and Claim 1 recites the process for making the compound of formula (I) comprising the cyclization of formula (II). The Examiner concludes therefore that the claim fails to recite essential elements for the improved or known process, such as the reaction conditions (i.e. solvent, temperature, reagent, etc.).

10/528,612 06/25/2007 02/26/2007

Applicants respectfully disagree and argue that the claim is already both clear and definite.

The presently claimed invention relates to the process of preparing a compound of formula (I):

by cyclising a compound of formula (II):

The prior art process for preparing these compounds is given at the top of page 2:

I.e. reacting the aldehyde with the azide. The disadvantage of this prior art process is given under the scheme where it is stated that this process is difficult to effect as it may proceed explosively.

The improvement to the process for making compounds of formula (I) is therefore to make these compounds via the cyclisation of a compound of formula (II) as opposed to the aldehyde / azide reaction shown above thus avoiding the use of explosive azides.

Applicants therefore consider that Claim 1 does in fact recites the essential elements of the claimed process, namely the (i) the starting material (the compound of formula (II)), (ii) the reaction (cyclisation) and (iii) the end product (the compound of formula (I)).

10/528,612 06/25/2007 02/26/2007

The term "cyclisation" itself is a term well known to the skilled person and means the formation of one or more rings in a hydrocarbon. The skilled person looking at formula (II) cyclising to make a compound of formula (I) would immediately understand what this meant, i.e. forming a ring in the following manner:

Suitable solvents/temperatures etc for effecting the cyclisation reaction are given in the specification on page 3, lines 4 to 10, but Applicants consider that they do not constitute essential elements which should be included in the claim. These are exemplary conditions, not essential elements

Applicants therefore respectfully submit that Claim 1 fulfills our obligations under 35 USC §112 second paragraph, all the essential elements are included, and respectfully request that the rejection is withdrawn.

# Claim Rejections - 35 USC § 102

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Soth et al., Canadian Journal of Chemistry, 1978, 56(10), pp. 1429-1434. The Examiner states that Soth et al. teaches the process of making 4H -thieno[3,2-b]pyrrole-5-caboxylic acid and esters comprising the cyclization reaction of N-acetyl-N-(2-formyl-3-thienyl)-glycine ethyl ester, see, e.g. Abstract, Accession Number 1979:103864 HCAPLUS; and also, Soth et al., Scheme 3, p.1431, compound (b).

In response to this rejection, Applicants have amended the definitions of  $R^4$  and  $R^5$  in claim 1 to recite that  $R^4$  and  $R^5$  are independently selected from halo. Basis for this amendment can be found at page 5. line 25 of the PCT application as published.

Applicants respectfully request that the rejection is withdrawn.

### VI. OBJECTION(S)

Claims 2, 3 and 12 are objected to as being dependent upon a rejected based claim.

In view of the amendments and arguments presented above, Applicants consider this is now most.

Application No. 10/528,612 Amendment Dated 06/25/2007 Reply to Office Action of 02/26/2007

The above amendments have been made without prejudice to Applicants right to prosecute any cancelled subject matter in a timely filed continuation application.

Applicants believe the application is in condition for allowance, which action is respectfully requested.

A petition for a 1 month extension of time is being filed herewith, the Commissioner is hereby authorized to charge any deficiency in the fees or credit any overpayment to deposit account No. 50-3231, referencing Attorney Docket No. 100837-1P US.

Respectfully submitted, /Lucy Padget/

MA 02451

Name: Lucy Padget

Dated: 25 June 2007
Reg. No.: L0074
Phone No.: 781-839-4182
Global Intellectual Property, Patents,
AstraZeneca R&D Boston,
35, Gatehouse Drive,
Waltham.